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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,052	06/29/2001	Frank J. Bunick	MCP-281	9476
27777 7590 02/07/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON			EXAMINER	
			OH, SIMON J	
ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT	PAPER NUMBER
NEW BRONS			1618	
			MAIL DATE	DELIVERY MODE
			02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
_	09/896,052	BUNICK ET AL.				
Office Action Summary	Examiner	Art Unit				
	Simon J. Oh	1618 ·				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on <u>28 January 2008</u> .  2a) This action is <b>FINAL</b> .  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-25 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-25 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119	·					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Interview Summary					
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:					

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## **DETAILED ACTION**

# Papers Received

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, and request for continued examination, all received on 28 January 2008.

# Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 January 2008 has been entered.

## Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-25 under 35 U.S.C. 103(a) over Lee (U.S. Patent No. 6,060,078) in view of Mehta (U.S. Patent No. 4,800,087), Silva *et al.* (U.S. Patent No. 4,753,790), and Mackles (U.S. Patent No. 4,260,596) is maintained.

## Response to Arguments

Applicant's filed on 28 January 2008 have been considered but are not found to be persuasive. The applicant argues that because the Mehta patent teach only taste masking and

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does not address texture masking, it cannot be combined with the Lee patent because of an absence of motivation. However, it has been clearly set forth that the decision in *KSR*International Co. v. Teleflex Inc. forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See Ex parte Smith, --USPQ 2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396).

Furthermore, the applicant has failed to establish where it is necessary that a prior art reference is required to solve the same problem as that addressed by the instant claims. The Mehta reference is very clear that the pharmaceutical cores taught therein may be further coated with candy, and it is the position of the examiner that such a disclosure brings the subject matter of the Lee patent into consideration, since that reference teaches a candied pharmaceutical formulation.

The coating of pharmaceutically active agents is well known in the art for various purposes, including taste masking, texture masking, and to effect a differential rate of release. It is the position of the examiner that one of ordinary skill in the art can use coated pharmaceutical agents in place of uncoated pharmaceutical agents for any of the aforementioned purposes.

It is wholly insufficient to point out differences in the prior art alone and then make the allegation that because of how the prior art differs from the subject matter of the instant claims that the instantly claimed invention is patentable or that the prior art references cannot be properly combined. Such an argument is utterly unconvincing, when the obviousness analysis set forth by *Graham v. Deere* calls for not only ascertaining the differences between the art and the instant claims, but also resolving those differences in view of what is known to one of ordinary skill in the art at the time the instant application was filed. As the latter part of that

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analysis is absent from the applicant's arguments, the applicant has failed to properly rebut the

prior art rejections of record. Therefore, the claims remain rejected.

Correspondence

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The

examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh Examiner

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sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER